



USAMRAA

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A Principal Assistant Responsible for Contracting Welcome

Kenneth B. Connolly

Business Alliances – Shrinking resources, global markets, global competition, impatient investors, unpredictable customers, and waning employer-employee loyalty, make it very difficult to operate, let alone expand, an enterprise with any certainty without first having forged and continuing to forge business alliances. It was Demosthenes (384 BC – 322 BC), who said “small opportunities are often the beginnings of great enterprises”.

Business alliances provide the flexibility and resources to capture those “small opportunities”, that would not be possible using the resources of a single entity or business. There are various types of business alliances ranging from formal contracts and trade associations to the more informal social, religious, and civic associations. It is the shrewd and successful entrepreneur who can forge business alliances that benefit all parties in the alliance. Solid business alliances are forged from trust and accepting the objectives and aspirations of the parties making up the alliances, which takes many years to develop, much like the work of a blacksmith making a fine sword. The blacksmith takes layers of various metals and through heat, hammering, grinding, and polishing, and over time takes those separate layers of metal and turns them into a very strong sword. Just like making the sword, there is a lot of work combining various layers of independent organizations in such a way that a strong business alliance is forged. In this addition of the Acquisition Business Journal, we will further explore forging business alliances.

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Editorially Speaking

Tish Nelson

In the “do more with less” environment of today, the Government is thinking and operating more like a business. This creates a considerable challenge and an opportunity to develop and leverage new business solutions. A viable option is building alliances with industry, academia, state and local governments, community, as well as other Federal Government agencies. Partnering is not a new concept to the Government, it is essential to maximize mission capability and is a cost-saving approach for all partners.

To position yourself as a partner, preliminary groundwork will include milestones such as:

- ◆ A fresh proactive attitude.
- ◆ Motivated and committed planning team.

Representatives from each of these offices would prove beneficial: Business Development Office (such as the one being established at USAMRAA and will be outlined in a separate article), legal, public affairs, engineering, security, safety, comptroller, contracts, installation organizations, and tenant activities. This team will assess organization priorities, security requirements, what each organization/installation has as assets to offer to partners, defining needs of the installation and charting possible teaming approaches to benefit both partners.

◆ Business Development Office/Marketing Team with a uniform message. Persuasive outreach people representing all facets of the installation's population and needs. All leaders and managers must be dedicated to the effort.

Articles reflecting the various alliances formed to cultivate a win-win solution for government, industry and community are included in this journal.

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A Teaming Approach

Dr. Mark Dertzbaugh

With the ever-increasing demand on Government personnel and resources coupled with the decreased budgets, teaming solutions are vital to the survival of missions. The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has experienced a massive increase in the demand for evaluating the efficacy of potential medical countermeasures in animal models against biological threat agents. In particular, there has been an increased demand for performing nonhuman primate (NHP) studies, which require a large amount of space. USAMRIID currently has insufficient capacity to meet the demand, which could have a major impact on the institute's ability to support the customers' needs.

As part of our new Biodefense Partnership Initiative with the National Institutes of Allergy and Infectious Diseases (NIAID), the NIAID agreed to assist USAMRIID in expanding its BSL-3 animal holding capacity in exchange for access to our facilities and our unique expertise. Consequently, \$950,000 in DOD funding was provided by the Medical Biological Defense Research Program (MBDRP) to support construction of the building shell and the NIAID contributed \$6,000,000 to construct the modular equipment that would be used to hold the animals. A contract was awarded at the end of FY2002 to begin construction of the Animal Facility. When completed in early summer of 2004, it is anticipated that BSL-3 holding capacity will be expanded by over 400 NHPs.

Dr. Mark Dertzbaugh is the Chief, Research Plans & Programs, at the U.S. Army Medical Research Institute for Infectious Disease, Fort Detrick, Frederick Maryland.

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Contracting Community Partnership

Tish Nelson

The Fort Detrick Contracting Community recently signed a charter that created a partnership that will better serve the needs of the local business community through a single-voice industrial liaison and Web site access.

Fort Detrick is unique in that it has multiple contracting offices. They include U.S. Army Medical Research Acquisition Activity, National Cancer Institute-Frederick, Department of Veterans Affairs, Naval Medical Logistics Command, Defense Supply Center-Philadelphia, Technology Applications Office and the Science Applications International Corporation-Frederick.

Although Fort Detrick annually awards about \$40 million to the local community, there has been a barrier for local business on how to do business with the government and how to locate various contracting opportunities. A web site is currently under construction that will include links to

the partners and their points of contact.

Additional information on this partnership is available from U.S. Army Medical Research Acquisition Activity, Ms. Vicki Yontz, Customer Representative, at 301-619-2112.

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Technology Investment Agreements

Burnie Clutz

Technology Investment Agreements (TIAs) are a class of assistance agreements derived from the authority of 10 U.S.C. 2371. TIAs are a form of "other transactions", meaning they are not grants, cooperative agreements or contracts, but, rather are other than those kinds of instruments. TIAs may be used to carry out basic, applied, and advanced research projects, when it is appropriate to use assistance instruments and the research is to be performed by for-profit firms or by consortia that include for-profit firms, particularly firms that traditionally have not done business with the Government.

TIAs are not governed by the Federal Acquisition Regulation (FAR), Army Federal Acquisition Regulation (AFAR), or Defense Federal Acquisition Regulation (DFAR). This permits a certain amount of negotiating flexibility, particularly in the areas of financial management systems, cost principles, and rights to technical data and computer software thus reducing barriers to encourage participation by for-profit firms. Additionally, TIAs emphasize a relationship of teamwork and Government insight into projects rather than oversight.

Statute requires that TIAs be competed to the maximum extent practicable. The competition requirement is met by indicating in Broad Agency Announcements the potential to make awards of TIAs. In deciding if a TIA is an appropriate instrument for award, consideration must be given to the nature of the project, the type of recipient, the recipient's commitment to cost sharing as a 50/50 cost share is often most practical, and the degree of involvement the Government program official can afford as TIAs rely more than traditional instruments on programmatic involvement before and during program execution.

Although TIAs are utilized to engage the participation of for-profit organizations in Government research efforts, TIAs may not provide for the payment of fee or profit to the recipient and may not be used to carry out a program where payment of fee or profit is necessary to achieving program objectives.

There are several advantages to using TIAs when conditions permit. TIAs attract technology firms that normally avoid DOD business, they maximize tailoring and minimize "contractual" kinds of concerns, they leverage research dollars through cost sharing, they harness the incentive to develop

and commercialize technology, and they promote relationships of trust and cooperation with industry.

The U.S. Army Medical Research and Materiel Command is continually searching for partnerships that will benefit the industry and the Army.

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Small Business Outreach

Jerome Maultsby

One of my priorities as the Associate Director, Small and Disadvantaged Business Utilization is to provide outreach opportunities to small business concerns. It is worth noting that US Army Small Business Programs include: Women Owned Small Business, Certified 8(a), Small Disadvantaged Business, HUB Zone Small Business, Veteran-Owned, Service Disabled Veteran-Owned and Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

In today's competitive business environment we often read about testimonials from entrepreneurs who appear to possess secret ingredients that translate into increased business opportunities. Although the nation's economic picture is not bright, there continues to be a sense of optimism that small businesses can be a catalyst in helping to rebuild the economy. Since September 2002, I have made a concerted effort to increase the quantity and quality of outreach activities for prospective contractors who have a desire to establish strategic business alliances with the Fort Detrick and US Army Medical Research and Materiel Command (USAMRMC). Some of the outreach efforts include attendance and participation in several USAMRMC, US Army Medical Research Acquisition Activity (USAMRAA) and Frederick County sponsored workshops and symposiums, as well as providing general information regarding understanding the procurement process. I must admit that providing information of this nature on a daily basis is time consuming, but a critical part of my duties. In fact, I'm committed to ensuring that any small business entity that has a relevant product or service that can contribute to a Commander's/Director's mission success, be given an equitable opportunity to participate in the procurement process. From my vantage point, as the Associate Director, SADB, I have concluded that in my quest for continuous improvement, there are several initiatives that can be designed to strengthen the outreach efforts. Some of these initiatives are already in the beginning stages of implementation e.g., creation of a USAMRMC Small Business Web Site, USAMRMC Small Business Marketing Brochure and an updated and comprehensive HBCU/MI

Capabilities Directory. These three initiatives are intended to provide improved access to valuable information and resources from not only The Department of Defense, but also other governmental and non-profit organizations.

I'm a firm believer in embracing new concepts to the extent that future outreach efforts will consist of a combination of technology integrated with personal interaction. Relying exclusively on technology to boost outreach to small businesses is not conducive to building long-term alliances. USAMRMC's Principal Assistant Responsible for Contracting and I have discussed other methods that will permit me to further expand outreach efforts to the local business community. I have spoken to Frederick's Chamber of Commerce President on a couple of occasions and have received his support in working towards providing relevant business related information to the community. I have also spoken to and am scheduled to meet with the Frederick's Director of Economic Development about how we can partner and co-sponsor future outreach venues. In today's sluggish economy, businesses, especially small businesses, are eternally optimistic regarding their survival. They are not requesting any hand-outs, but desire equal access to information and opportunities to learn about the general information and the subtle nuances associated with government contracting opportunities. The recent signing of the Fort Detrick Contracting Community Charter is significant, because it clearly demonstrates the commitment among neighboring procurement activities to actively participate in outreach efforts.

I remain committed to working with the USAMRMC community in hopes of adding value to not only meeting our Department of Army mandated small business goals, but to also be a clearing house of small business information and guidance.

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Maryland Partnership with Military Installations

Tish Nelson

The state of Maryland has published a Maryland Partnership Guide for Military Facilities. This guide provides ways to approach partnerships between federal, state, and local government organizations, as well as not-for-profits and for-profit organizations.

Maryland realizes the need to partner and to be creative and flexible to meet the challenging partnering opportunities available with military organizations. Various representatives of Frederick are meeting to see what opportunities for partnering are available.

Compliance and the Extramural Research Community

Carol Blum

The universities were willing but couldn't comply. The USAMRMC staff understood but policy required it. While not the most auspicious beginning for a partnership, an impasse over the reimbursement of medical costs to human research subjects served as the point of departure for a collaboration between the USAMRMC and the extramural academic research community. Long engaged in cooperative scientific ventures, the research compliance and acquisition staff from USAMRMC and university members of the Washington-based Council on Governmental Relations (COGR) met in April 2003 to explore new ways to meet the Command's policies governing research.

The Council on Governmental Relations (COGR), a membership association of the top 150 research-intensive universities in the US, works with federal agencies to develop a common understanding of the impact that the agencies' policies, regulations and practices may have on the research conducted by its membership. Since June 2002, COGR representatives and Command staff wrestled with the requirement to reimburse human research subjects for the treatment costs for research-related injury or illness. Universities tried, and failed, to estimate these costs or find an insurance policy for clinical trials. Some state-assisted universities simply could not agree to the direct reimbursement because of state statutory prohibitions. The commitment of Command staff to work through the problem resulted in an approach that meets the Army's commitment to provide care at no cost while recognizing the variety of university mechanisms used to manage research-related injury.

The discussions over the reimbursement question brought to light other USAMRMC policies and procedures that in some cases conflicted with university operations or, in others, replicated university policies and procedures. As these issues threatened to bog down negotiations and undermine the scientific cooperation, two things became clear. The relationship between the Command and the universities – between grantor and grantee – was becoming more complex and would benefit from regular communications between USAMRMC and the universities.

And there are opportunities for collaborations to streamline and simplify processes to meet the Command's compliance requirements. The reimbursement requirement provides an example of the type of technical question or issue that regular communication can address and resolve quickly. Its resolution, however, encouraged an examination of the broader foundation and overall structure of the relationship and brought these long-standing science partners to the business table.

The Command's sponsorship of extramural, university-based biomedical research has expanded over the past ten years, particularly with the growth of the Congressionally Directed Medical Research Programs. With increased support, the science has matured and the most-promising projects are beginning to move from the laboratory to clinical trials – from basic to more applied research. In the process of reviewing the assistance agreement's terms and conditions for these new types of projects, the universities discovered some clauses like the reimbursement of subjects that posed new management problems for the support of research in clinical settings.

The basic regulatory framework is clear. The Federal Common Rule for the Protection of Human Subjects (32 CFR 219) as implemented in the Department of Defense Directive for the Protection of Human Subjects and the Ethical Conduct of Research (DODD 3612.2) is very familiar to university researchers. Like DODD 3612.2, university policies implement the Common Rule. But changes in the research environment and the public's expectations for the conduct of clinical trials led the Command's Human Subjects Research Review Board (HSRRB) to address these changes by adding to and revising its policies to provide additional protections for the subjects and to ensure the integrity of the research enterprise. Universities engaged in a very similar process by adding policies and procedures that manage, among others, research misconduct, investigator financial conflicts, and data retention and access. As the extramural research grew, USAMRMC extended its policies, designed originally to manage its intramural research programs, to the extramural community under the umbrella of human subjects research review. As a consequence, the HSRRB now finds itself reviewing a greater number of proposals in an expanding regulatory framework. Paradoxically, the universities are conducting the same or markedly similar reviews before proposals are submitted to the Command. This duplication and burden on the staffs threatens to slow approval and delay research.

The Command staff and university representatives who gathered at Fort Detrick in April for the first of what we anticipate to be many such discussions agreed that new compliance and related business models should be explored to mitigate the workload of the HSRRB and university Institutional Review Boards, streamline the agreement management and, as a consequence, strengthen the partnership. We have identified opportunities for examining the broad framework of the relationship – e.g., university presentations at the HSRRB Off-Site meeting – and mechanisms for proposing technical changes to acquisitions instruments – e.g., offering formal comment on the broad agency announcements or program announcements. The bridge has been built – we just have to cross.

Carol Blum, Council on Governmental Relations
Washington DC 20005

Partnering through Cooperative Research and Development Agreements

Jay Winchester and Sara Baragona

A Cooperative Research and Development Agreement (CRADA) is a written legal agreement that allows federal laboratories to collaborate and work with US industries, universities and other organizations in conducting specific research and development efforts that can benefit both the Army and the civilian world.

Created as a result of the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986, the CRADA allows flexibility in organizing project contributions, intellectual property rights, and in protecting proprietary information and research that is a result of the agreement and government/organization partnership.

When a party enters into a CRADA, they will acquire obligations in addition to rights. A federal laboratory may contribute to a CRADA in several ways. Federal employees or contractors may be assigned to contribute to the research and development process of an agreement as part of their official duties. The government may also purchase tangible and intangible property (such as intellectual property, facilities and equipment), as well as accept funds to contribute to the CRADA. Non-federal partners may also supply funds, personnel, services, equipment, facilities, intellectual property, or other resources needed to conduct an agreement.

When a CRADA yields beneficial research and/or developments, the results can then be patented and licensed. Therefore, it is important that all parties entering into an agreement ascertain that the CRADA clearly defines the rights and protections of the parties with respect to inventions, patents, copyrights, and trade secrets. This includes all intellectual property developed before the agreement by one party and disclosed or licensed to another party, or developed solely or jointly by the parties in the performance of the CRADA.¹

While the work conducted under a CRADA allows the Army to meet their mission of defense, the CRADA also facilitates and encourages the transfer of commercially useful technologies from federal laboratories to the private sector. This dual use lends an even greater benefit when the resulting research and possible developments lead towards generating jobs, taxes, and thriving companies.

An example of a successful partnership can be seen in the collaboration of the Walter Reed Army Institute of Research (WRAIR) and the Program for Appropriate Technology in Health (PATH). Funded by the Gates Foundation, PATH established the Malaria Vaccine Initiative (MVI), which aims to accelerate the development of promising malaria vaccines. The original malaria vaccine, which was created under a CRADA

with WRAIR and GlaxoSmithKline Biologicals, only provides temporary immunity. While creating a new and more effective malaria vaccine will protect military personnel in malaria endemic regions, it will also be beneficial to third world counties. PATH seeks to ensure that the vaccine will be available for citizens of developing countries, who suffer the greatest casualties due to the parasitic infection.

¹ Cooperative Agreements & Other Transactions. Federal Publications Inc. 1998.

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Assistance Agreements

Tish Nelson

The US Army Medical Research Acquisition Activity uses Broad Agency Announcements (BAAs) and Program Agency Announcements (PAAs) to solicit partners for a multitude of requirements. These announcements list research areas that are of interest to the Army, Congress or other Agencies as specifically stated in the announcement. A streamlined approach for response has been honed over the years. A two-tiered review process is used to evaluate proposals within the US Army Medical Research and Materiel Command (USAMRMC).

USAMRMC scientists and/or outside experts conduct the first tier, a peer review, evaluating factors such as research strategy and objectives, impact, Principal Investigator and key personnel qualifications, facilities and budget.

The second tier, a programmatic review, is conducted by a team, which may consist of expert USAMRMC scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians, consumers, or a combination thereof. Programmatic review is primarily concerned with three criteria: peer review recommendations, programmatic priorities and portfolio balance.

After this two-tiered evaluation, proposals recommended for funding are prioritized. Awards are then dependent on the availability of funds, fulfillment of requirements and priorities determined to exist at the time of award. Of course, award is always dependent upon demonstration by the applicant that they have fulfilled the USAMRMC Regulatory Compliance requirements for research involving human subjects, research involving animals, facility safety plan and certificate of environmental compliance.

This process leads to the award of contracts or assistance agreements (grants and cooperative agreements). Assistance agreements are awarded in compliance with Department of Defense Grant and Agreement Regulations, DoD 3210.6-R. The grant is accomplished by the recipient with a focus of the research outlined in the proposal and has a public purpose of support. The cooperative agreement is a team effort between the recipient and the sponsoring laboratory, also with a public purpose of support. The sponsoring laboratory has substantial involvement in the project. Assistance agreements have created great partnerships over the years for enumerable projects. The assistance agreement outlines responsibilities and addresses pertinent issues such as patents, intellectual property, reports and publications, to name a few.

Assistance Agreements have forged many partnerships over the past years. MRMC looks forward to teaming with you on future projects. Be sure to look for the BAAs and PAAs on our homepage: www.usamraa.army.mil.

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"Partnering has proven itself one of the most powerful business tools for dealing with fast changing markets, technologies and customers. As the global economy speeds up, partnering is becoming the weapon of choice for today's successful competitors."

Curtis E. Sahakian

ABJ Editorial Staff POC Information, etc.

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Acquisition Business Knowledge Bank

Books and Publications:

Power Partnering: A Strategy for Business Excellence in the 21st Century by Sean Gadman

Partnering Intelligence: Creating Value for Your Business by Building Smart Alliances by Stephen M. Dent

Let's Go Into Business Together: 8 Secrets to Successful Business Partnering by Aziela Jaffe

Government-Industry Partnerships for Development of New Technologies by Charles W. Wessner. National Research Council

A Maryland Partnership Guide for Military Facilities prepared under an agreement with The Army Alliance and The Technology Management Group of Geo-Centers, Inc.

Articles:

Stephen M. Dent, Partnership Continuum, Inc.

<http://www.partneringintelligence.com/>

Internet and Web Locations:

US. Army Medical Research and Material Command

<http://mrmc-www.army.mil>

US. Army Medical Research Acquisition Activity

<http://www.usamraa.army.mil>

http://www.amc.army.mil/amc/command_counsel/partnering.html

Partnering for Success: A Blueprint for Promotion Government - Industry Communication and Teamwork

<http://www.acq-ref.navy.mil/reflib/partweb.pdf>

Strengthening Relationships: Partnering with Industry

<http://www.wifcon.com/fa.htm>

Grants and Cooperative Agreements Informational Website

http://www.defenselink.mil/news/Feb1999/b02031999_bt045-99.html

DOD Seeks Additional Industry Partnerships on Leading Edge Technologies

<http://www.corporate-partnering.com>

Corporate partnering information center